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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,602	08/07/2003	Ye Sun Han	8111-032-999	3399

20583 7590 10/11/2005

JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/637,602

Applicant(s)

HAN ET AL.

Examiner

Timothy M. Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2 and 3 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7 August 2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Non-Final Office Action is responsive to the communication received September 22, 2005. Claims 2 and 3 are under examination. Claims 1 and 4 are withdrawn.

#### ***Election/Restrictions***

Applicants' election of Group II, comprising an agent that increases intracellular calcium concentration, is acknowledged. Applicants' traverse the restriction requirement arguing that searching a complex, and a method for controlling movement of the complex (i.e. Groups I-III), would not create an undue burden. The Examiner respectfully disagrees. Joining Groups I-III would create an undue burden because it would require a search of different method steps and method functions. Moreover, Groups I-III are patentably distinct. For example, Group I is related to Group II as product and process of using the product. For at least these reasons, the restriction requirement is maintained.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is indefinite in that the recitation of "controlling" in line 1 fails to indicate whether the movement of the claimed complex is inhibited or catalyzed. Claim 2 is further indefinite in the recitation of "controls" in line 3. This language fails to indicate whether the agent increases or decreases the calcium ion concentration. Appropriate correction is

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required. For purposes of examination, both “controlling” and “controls” have been interpreted as indicating an increase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.*** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Undue experimentation is defined by the following factors: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Here, the breadth of the claims reads on a method for inhibiting (i.e. controlling) movement of the HBVPol/p11 complex into the nucleus of a HepG2 cell comprising administering an agent that increases intracellular calcium. The specification teaches that increasing intracellular calcium, such as by valinomycin (p. 11), prevents the movement of the HBVPol/p11 complex into the nucleus. However, the state of the art at the time this application was filed contradicts this teaching. Research shows that treating HepG2 cells with valinomycin does not prevent HBV replication (see e.g. Schneider et al. (US 2002/0045191 A1) paragraph

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0050-0051, Figures 10-11; and J. Virol. (July 2003) 77, 14, 7713-7719, Fig. 2). Because HBV replication involves the movement of HBV into the nucleus, the failure of valinomycin to prevent replication indicates that it also fails to prevent the movement of the HBVPol/p11 complex. One skilled in the art would not therefore be able to predict how the movement of the HBVPol/p11 complex can be inhibited by increasing intracellular calcium. Based on the foregoing, one skilled in the art would have to invest undue experimentation in order to make and use the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claims 2 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Schneider et al. (US 2002/0045191 A1).***

Claims 2 and 3 are drawn to a method for controlling the movement of the HBVPol/p11 complex into the nucleus of a HepG2 cell comprising administering an agent that increases intracellular calcium in the HepG2 cell. Schneider et al. disclose treating HBV-infected HepG2 cells with valinomycin (paragraph 0051 and Fig. 11). Thus, Schneider et al. anticipate the subject matter of claims 2 and 3.

Note that claims 2 and 3 have been construed to simply require administering a calcium-increasing agent to a HepG2 cell. No patentable weight has been given to the limitation of controlling movement of the HBVVPol/p11 complex into the nucleus.

***Conclusion***

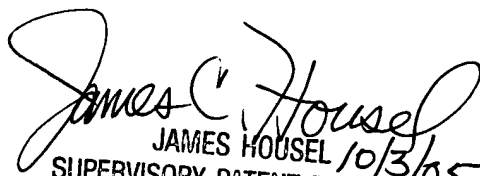
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown  
Examiner  
Art Unit 1648

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9/30/05